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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,249	05/03/2001	David F. Woodward	D2910	6273

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/848,249

Applicant(s)
Woodward et al.

Examiner
Zohreh Fay

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1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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Claims 1-23 are presented for examination.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 14-17 and 21 are rejected under 35 U.S.C. 102 (b) as being anticipated by Neumann. Neumann teaches the use of an alpha-2-adrenergic agonist and a fatty acid component in a pharmaceutical formulation. See column 4, lines 24-25 and 41-60.

Claims 1, 2, 5, 6, 9-17, 20-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by DeSantis Jr. et al.. DeSantis et al. Teach the use of clonidine with a fatty acid prostaglandin in a pharmaceutical formulation for the treatment of glaucoma. The above reference makes clear that prostaglandin has therapeutic effect. See column 2, lines 25-37. The topical ophthalmic use is also taught in claims 1 and 13.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 18, 19, 22 and 23 are rejected under 35 U.S.C. 103 as being unpatentable over WO 0044/355. The WO patent teaches the use of an alpha-2-adrenergic agonist in combination with a fatty acid in a pharmaceutical formulation. See page 4, lines 22-28, page 7, lines 18-22,

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page 10, lines 11-13, page 20, example 1L, Page 22, example 2 and page 23, lines 2-6. The above reference differs from the claimed invention in the presence of the specific fatty acids of claims 7 and 8, the addition of another agonist of claim 18, the additional acid of claim 19 and the specific agonist and acid of claims 22 and 23. It would have been obvious to a person skilled in the art to substitute one fatty acid for another considering that the prior art on page 22, example 2 teaches the use of different fatty acids within the chain length of the claimed invention in combination with an alpha-2-adrenergic-agonist to lower the solubility of the alpha-2-adrenergic agonist. It would have also been obvious to add another agonist or fatty acid to the composition considering that the addition of components with the same character is merely the additive effect of each individual component.

One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use alpha-2-adrenergic agonist in combination with fatty acids in order for the fatty acid to lower the solubility of the alpha-2-adrenergic agonist. The substitution of one fatty acid or alpha-2-adrenergic agonist for another would have been obvious to a person skilled in the art in the absence of evidence to the contrary. There is no evidence of record to demonstrate the advantages of using the claimed fatty acid and alpha-2-adrenergic agonist over the similar fatty acids and alpha-2-adrenergic agonists. The presented data in table 1, are confusing, as they show higher sedation score for bromonidine tartrate over the claimed complex bromonidine-linoleic acid. Applicant has presented no convincing evidence to establish the

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unexpected or unobvious nature of the claimed invention, and as such, claims 8, 9, 18, 19, 22 and 23 are properly rejected under 35 U.S.C. 103.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200



Z.F

November 1, 2002